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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/853,985	05/11/2001	Denes Marton	6006-023	6863

7590

03/01/2004

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EXAMINER

NERBUN, PETER P

ART UNIT	PAPER NUMBER
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3765

DATE MAILED: 03/01/2004

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/853,985

Applicant(s)

MARTON, DENES

Examiner

Peter P Nerbun

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 January 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-6,8-18 and 21-28 is/are pending in the application.
- 4a) Of the above claim(s) 3,4,8,9,16-18,22 and 23 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 26-28 is/are allowed.
- 6) ☒ Claim(s) 1,5,6,10-13,24 and 25 is/are rejected.
- 7) ☒ Claim(s) 14,15 and 21 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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Claims 26-28 are allowed.

Claims 14,15, and 21 are objected to under 37 CFR 1.75 as being a substantial duplicate of claims 26,27, and 28. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1,5,6,10-13,24, and 25 are rejected under 35 U.S.C. 102(e) as being anticipated by McGuinness, taken as applied in the previous Office action (paper no. 10). The patent to McGuinness discloses an implantable medical device comprising a self-supporting structural member 10, Fig. 1 fabricated of a plurality of laminated layers of at least one biocompatible material (316 stainless steel), wherein the plurality of

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laminated layers forms a substantially monolithic structure. Note col. 6, lines 30-45 of McGuinness which state that the stent 10, Fig. 1 can be made by performing the steps of providing a flat sheet of biocompatible material and laser milling the flat sheet of material to form the pattern depicted in Fig. 2A. Thereafter the upper and lower edges of the milled sheet are joined together by rolling the sheet of material about its longitudinal axis to form a cylinder. The two edges of the rolled sheet can be joined by welding. (see col. 6, lines 31-38 of McGuinness). The term "laminated" is defined as being made by uniting superposed layers of one or more materials. The milling process referred to above creates two distinct layers – a foundation layer and a patterned layer that is situated on top of the foundation layer. Thus a plurality of layers is formed by the milling process. The plurality of layers are laminated layers because they are united together in the region where the base of the patterned layer unites with the upper surface of the foundation layer. Therefore a plurality of superposed layers are formed in a united relationship and thus constitute laminated layers. The plurality of laminated layers forms a substantially monolithic structure since the layers consist of a single unit (i.e. a single tubular piece of stainless steel that has been chemically etched to define the layer structure).

Claims 3,4,8,9,16-18,22, and 23 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 9. The examiner made the restriction (election) requirement FINAL in paper no. 10.

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Applicant's arguments filed January 16, 2004 have been fully considered but they are not persuasive. In the last sentence on page 7, applicant states that McGuinness fails to disclose an implantable medical device comprising laminated layers. As noted above McGuinness states that the stent 10, Fig. 1 (i.e. an implantable device) can be made by performing the steps of providing a flat sheet of biocompatible material and laser milling the flat sheet of material to form the pattern depicted in Fig. 2A. Thereafter the upper and lower edges of the milled sheet are joined together by rolling the sheet of material about its longitudinal axis to form a cylinder. The two edges of the rolled sheet can be joined by welding. (see col. 6, lines 31-38 of McGuinness). The term "laminated" is defined as being made by uniting superposed layers of one or more materials. The milling process referred to above creates two distinct layers – a foundation layer and a patterned layer that is situated on top of the foundation layer. Therefore a plurality of superposed layers are formed in a united relationship to thus constitute laminated layers. Applicant further states that the aforementioned layers do not form a monolithic structure. The plurality of laminated layers forms a substantially monolithic structure since the layers consist of a single unit (i.e. a single tubular piece of stainless steel that has been chemically etched to define the layer structure). On page 8, lines 3-9 applicant states that McGuinness discloses the tubular bodies as being "milled or etched to have a pattern that appears as a set of cylindrical elements, typically each of which has a sinusoidal shape, joined by connecting elements which comprise articulated arms and substantially straight connecting rods". Applicant further states that "This passage confirms that which is described in the drawings, a series of

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rings or cylindrical elements (see Fig. 1A) that are joined by connecting elements to form a tubular structure". The examiner agrees with applicant's characterization of the structure to the extent that it describes the shape of the patterned layer located on the surface of the foundation layer. Together these layers form a plurality of laminated layers forming a monolithic structure as explained earlier within this paragraph.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

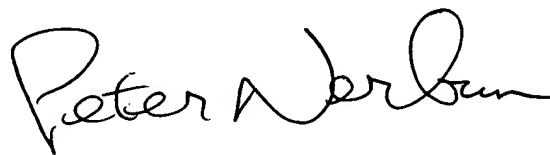
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter P Nerbun whose telephone number is 703-308-0955. The examiner can normally be reached on M-F (1st Week) M-Th (2d Week).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John J Calvert can be reached on 703-305-1025. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Peter Nerbun
February 26, 2004

A handwritten signature in black ink that reads "Peter Nerbun". The signature is fluid and cursive, with the first letter of each name being capitalized and prominent.

Peter Nerbun
Primary Examiner